Applicant: Barberich et al.
Title: METHOD FOR TREATING ASTHMA USING OPTICALLY PURE (R)-ALBUTEROL

Enclosed: Division-Continuation Program Application Transmittal Form (In duplicate)
Application which includes: Specification (5 Pages); claims (2 pages) and Abstract (1 page)
Declaration
Express Mail Certificate
Check in the amount of $365.00

08/335480

0701.027C/PEH/tfp

November 7, 1994

SEP. 3, LR

Exhibit A

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

TC

NUMBER	RECEIPT DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
35,480	11/07/94	BARBERICH T	0701.027C

03A1/1216

PHILIP E HANSEN
KEIL AND ROTHENBERG
COLUMBIA CIRCLE
ALBANY NY 12203-5160

0000

12/16/94

NOTICE OF INCOMPLETE APPLICATION FILED UNDER 37 CFR 1.60

A filing date has NOT been assigned since 37 CFR 1.60 has not been complied with for the reason(s) indicated below:

1. ☐ A copy of the specification (description and claims) filed in the parent application:
   a. ☐ is missing.
   b. ☒ has page(s) _____ missing.
   c. ☐ has the description of the invention missing.
   d. ☐ has claim(s) _____ missing.

2. ☐ A copy of the drawings as filed in the parent application is missing.

3. ☐ A copy of any amendments referred to in the oath or declaration filed to complete the parent application is missing.

4. ☒ A statement is missing that the application papers filed are a true copy of the prior application, and that no amendments referred to in the oath or declaration filed in the prior application introduced new matter. Such statement must be made by the applicant or applicant's attorney or agent and must be a verified statement if made by a person not registered to practice before the United States Patent and Trademark Office.

5. ☐ Other:

The filing date will be the date of receipt of the items required above unless otherwise indicated. Any assertions that the items required above were submitted, or explaining the delay in supplying the omitted items, must be by a petition directed to the attention of the Office of the Assistant Commissioner for Patents. Any such petition must be accompanied by the $ _____ petition fee (37 CFR 1.17(i)(1)). If the petition states that the application is complete, a request for refund of the petition fee may be included in the petition.

All of the items noted above must be submitted within TWO MONTHS of the date of this notice, or the application will be returned upon request or otherwise disposed of.

Direct the response and any questions about this notice to, Attention: Application Processing Division, Special Processing and Correspondence Branch.

6

A copy of this notice MUST be returned with the response.

TC

Application Processing Division
(703) 308-1202

EXHIBIT C

0701.027C

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Barberich et al.

Serial No.: 08/335,480 Group Art Unit: 1205

Filed: November 7, 1994 Examiner:

Title: METHOD FOR TREATING ASTHMA USING OPTICALLY PURE (R)-ALBUTEROL

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as first class mail in an envelope addressed to: Hon. Commissioner of Patents and Trademarks, Application Processing Division, Special Processing and Correspondence Branch, Washington, D.C. 20231, December 21, 1994.

Philip E. Hansen
Agent for Applicant
Reg. No. 32,709

Date of Signature: December 21, 1994

To: Hon. Commissioner of Patents and Trademarks
Application Processing Division
Special Processing and Correspondence Branch
Washington, D.C. 20231

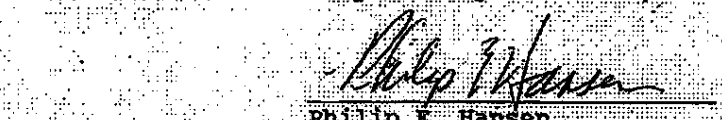
Response to Notice of Incomplete Application
Filed Under 37 C.F.R. 1.60

Dear Sir:

This is in response to the Notice of Incomplete Application in the above case. Response is required by February 16, 1995; this response is therefore timely filed. The Notice indicates that the copy of the specification filed on November 7, 1994 was missing pages 2 and 3. Enclosed herewith are copies of pages 2 and 3 and a copy of the Notice.

I hereby verify that the attached pages 2 and 3 are true copies of the latest inventor signed prior application, serial number 08/163,581 as originally filed on December 7, 1993 and further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Respectfully submitted,



Philip E. Hansen
Agent for Applicants
Reg. No. 32,700

Dated: December 21, 1994

Address for Correspondence:
Philip E. Hansen
Heslin & Rothenberg, P.C.
5 Columbia Circle
Albany, New York 12203-5160
Telephone: (518) 452-5600
Facsimile: (518) 452-5579

specific biological activity while the other enantiomer has no biological activity at all, or may have an entirely different form of biological activity.

Summary of the Invention

The present invention relates to a method of treating bronchial disorders, such as asthma, in an individual, by administering to the individual an amount of optically pure R(-) albuterol which is active in bronchial tissue sufficient to reduce bronchial spasms associated with asthma while minimizing side effects associated with albuterol. The method is particularly useful in treating asthma while reducing side effects, such as central nervous system stimulatory effects and cardiac arrythmia. In these applications, it is important to have a composition which is a potent broncho-dilator and which does not exhibit the adverse side effects of many beta-adrenergic drugs. A composition containing the pure R(-) isomer of albuterol is particularly useful for this application because this isomer exhibits these desired characteristics. The present method provides a safe, effective method for treating asthma while reducing undesirable side effects, for example, tremor, nervousness, shakiness, dizziness and increased appetite, and particularly, cardiac arrythmia, typically associated with beta-adrenergic drugs. In children, side effects such as excitement, nervousness and hyperkinesia are reduced when the pure isomer is

administered. In addition to the above, at certain levels racemic albuterol can cause teratogenic effects, which are believed to be associated with the S(+) isomer. Administering the pure isomer reduces the teratogenic potential which is associated with the S(+) isomer of albuterol.

Detailed Description of the Invention

The present invention relies on the bronchodilation activity of the R(-) enantiomer of albuterol to provide relief from bronchial disorders, while simultaneously reducing undesirable side effects, for example, central nervous system stimulatory effects and cardiac disorders, commonly experienced by albuterol users. In the present method, the optically pure R(-) isomer of albuterol, which is substantially free of the S(+) enantiomer, is administered alone, or in combination with one or more other drug(s) in adjunctive treatment, to an individual in whom asthma relief (e.g., relief from bronchial spasms, shortness of breath) is desired. The optically pure R(-) isomer of albuterol as used herein refers to the levorotatory optically pure isomer of α^1-[(tert-butylamino) methyl]-4-hydroxy-m-xylene-α, α'-diol, and to any biologically acceptable salt or ester thereof. The terms "optically pure" or "substantially free of the S(+) enantiomer" as used herein means that the composition contains at least 90% by weight of the R(-) isomer of albuterol and 10% by weight or less of the S(+) isomer. Optically pure albuterol is readily

OMB No. 0651-0011 (12/31/86)

DIVISION-CONTINUATION PROGRAM APPLICATION TRANSMITTAL FORM				ATTORNEY'S DOCKET NO. 0701.027C
DOCKET NUMBER	ANTICIPATED CLASSIFICATION OF THIS APPLICATION: CLASS	SUBCLASS	PRIOR APPLICATION: EXAMINER	ART UNIT
0701.027C	514		Henley	1205

To the Commissioner of Patents and Trademarks:

This is a request for filing a ☒ continuation ☐ divisional application under 37 CFR 1.60, of pending prior application serial no. 08/163,581 filed on December 7, 1993, of Timothy J. Barberich and James W. Young for Method for Treating Asthma Using Optically Pure (R)-Albuterol

1. Enclosed is a copy of the latest inventor signed prior application, including the oath or declaration as originally filed. I hereby verify that the attached papers are a true copy of the latest inventor signed prior application serial no. 08/163,581 as originally filed on December 7, 19 93, and further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Claims	(1) For	(2) Number filed	(3) Number extra	(4) Rate	(5) Calculations
	Total Claims	12 — 20=	0	X $22.00	$
	Independent Claims	3 — 3=	0	X $ 76.00	
	Multiple Dependent Claim(s) (if applicable)			+$ 240.00	
				Basic fee	+ $730.00
			Total of above Calculations =		
	Reduction by 1/2 for filing by small entity (Note 37 CFR 1.9, 1.27, 1.28) if applicable, affidavit must be filed also.				— 365.00
			Total National Fee		$ 365.00

2. ☒ The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. 08-1935. A duplicate copy of this sheet is enclosed.

3. ☒ A check in the amount of $ 365.00 is enclosed.

4. ☐ Cancel in this application original claims ______ of the prior application before calculating the filing fee. (At least one original independent claim must be retained for filing purposes.)

5. ☒ Amend the specification by inserting before the first line the sentence: This application is a ☒ continuation, ☐ division, of application serial no. 08/163,581, filed 12/7/93.

6. ☐ Transfer the drawings from the pending prior application to this application and abandon said prior application as of the filing date accorded this application. A duplicate copy of this sheet is enclosed for filing in prior application file. (May only be used if signed by person authorized by § 1.138 and before payment of issue fee.) Exhibit F

a. ☐ New formal drawings are enclosed.

b. ☐ Priority of application serial no. _____ filed on _____ in

_____ (country) is claimed under 35 U.S.C. 119.

☐ The certified copy has been filed in prior application serial no. _____

filed _____.

7. ☒ The prior application is assigned of record to Sepracor, Inc.

8. ☐ A preliminary amendment is enclosed.

9. ☒ A verified statement claiming small entity status is enclosed in parent application Serial Number 08/163,581, filed December 7, 1993 and is still proper.

10. ☐ Also enclosed _____

11. ☒ The power of attorney in the prior application is to

Hamilton, Brook, Smith and Reynolds, P.C.; an Associate Power of Attorney to Philip E. Hansen was filed July 14, 1993

a. ☒ The power appears in the original papers in the prior application.

b. ☐ Since the power does not appear in the original papers, a copy of the power in the prior application is enclosed.

c. ☐ Address all future communications to: (May only be completed by applicant, or attorney or agent of record)

Philip E. Hansen, Heslin & Rothenberg, P.C.

5 Columbia Circle

Albany, NY 12203-5160

11/7/94 (date) (signature) Philip E. Hansen

Address of signator: ☐ inventor(s) ☐ filed under § 1.34(a)

☐ assignee of complete interest

☒ attorney or agent of record

5 Columbia Circle

Albany, NY 12203-5160

1A

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/335,480	12/27/94	BARBERICH	0701.027C

EXAMINER: HENLEY III,R
ART UNIT: 1205
PAPER NUMBER: 7

12M2/0309

PHILIP E HANSEN
HESLIN AND ROTHENBERG
5 COLUMBIA CIRCLE
ALBANY NY 12203-5160

DATE MAILED: 03/09/95

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 2/10/95 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133.

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☒ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 1-12 are pending in the application.
   Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-12 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

Please see next page.

CLAIMS 1-12 ARE PRESENTED FOR EXAMINATION

Applicants' amendment filed November 7, 1994 and the Information Disclosure Statement filed November February 10, 1995 have been received and entered into the application. Accordingly, the specification at page 1, line 1 has been amended and as reflected by the attached, completed form PTO-1449, the submitted references have been considered.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-12 are rejected under 35 U.S.C. § 103 as being unpatentable over Muttari et al. (CK) in view of Brittain et al. (CB), Hawkins et al (CD) and Hartley et al. (CC).

Muittari et al. teach compositions containing salbutamol, i.e., albuterol, and additional active agents including hydroxyzine, an antihistamine, and the administration thereof to patients for the treatment of asthma.

The differences between the above and applicants' claimed subject matter lie in that the reference fails to highlight:

(1) the optically pure (R-) isomer of albuterol substantially free from the S(+) isomer;

(2) the claimed ingredient amounts; and

(3) the presence of an analgesic such as aspirin, acetaminophen or ibuprofen in the composition.

However, to the skilled artisan, applicants' claimed subject matter would have been obvious because:

(1) The expectation with regard to enantiomers is that their activities, as they pertain to living systems, are expected to be different. In re Adamson, 275 F.2d 952, 125 U.S.P.Q. 233 (C.C.P.A. 1960). The fundamentals of optical activity and stereoisomerism well known to persons having ordinary skill in the art. A person having ordinary skill in the art would have known how to resolve the racemic mixture and would have been motivated to do so with the reasonable expectation of achieving isolating the enantiomer having the optimum pharmacological activity. It appears as though applicant has determined experimentally what a person of ordinary skill in the art would have expected.

namely, that the racemic mixture of the prior art may be separate S(+) and R(-) enantiomers possessing differing degrees of pharmacological activity. This would have been an expected result. Also expected would have been that the R(-) enantiomer is the most active of the two given the teachings of Brittain et al. at page 144, "(1)" under the "Summary"; Hawkins et al. at page 857, column 1, lines 2-6; and Hartley et al. at page 895, column 2, second full paragraph. It is well established that expected beneficial results are evidence of obviousness of a claimed invention just as unexpected beneficial results are evidence of unobviousness. In re Skoll, 523 F.2d 1392, 187 U.S.P.Q. 481 (C.C.P.A. 1975); In re Skoner, 517 F.2d 947, 186 U.S.P.Q. 80 (C.C.P.A. 1975; In re Gershon, 372 F.2d 535, 152 U.S.P.Q. 602 (C.C.P.A. 1967).

(2) The determination of the optimum ingredient amount to administer would have been a matter well within the purview of the skilled artisan who would have been motivated to make such a determination in order to provide the most effective therapy possible; and

(3) Since a patient suffering from asthma often experiences discomfort upon respiration, the concomitant use of an analgesic to relieve such discomfort would have been an obvious selection and the skilled artisan would have been motivated to do so in order to provide the most effective therapy possible.

Claims 1-8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 5,362,755. Although the conflicting claims are not identical, they are not patentably distinct since chronic administration of R(-) albuterol and the attendant advantages thereof are clearly within the scope of the present claims.

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. *In re Vogel*, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.78(d).

Thus, for the above reasons, the claims are deemed to be properly rejected and none of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ray Henley whose telephone number is (703) 308-4652.

RAYMOND HENLEY, III
PRIMARY EXAMINER
GROUP 1200

Henley: rjh
February 24, 1995

TO SEPARATE, HOLD TOP AND BOTTOM EDGES, SNAP--APART AND DISCARD CARBON

FORM PTO-892 (REV. 3-78) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

NOTICE OF REFERENCES CITED

SERIAL NO.	GROUP ART UNIT	ATTACHMENT TO PAPER NUMBER
08/335,480	1205	10

APPLICANT(S): BARBERICH ET AL.

U.S. PATENT DOCUMENTS

*		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE IF APPROPRIATE
	A	5 362 755	11/94	Barberich et al.	514	849	
	B						
	C						
	D						
	E						
	F						
	G						
	H						
	I						
	J						
	K						

FOREIGN PATENT DOCUMENTS

*		DOCUMENT NO.	DATE	COUNTRY	NAME	CLASS	SUB-CLASS	PERTINENT SHTS. DWG.	PP. SPEC.
	L								
	M								
	N								
	O								
	P								
	Q								

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

R	
S	
T	
U	

EXAMINER: [signature] DATE: 2/24/95

*A copy of this reference is not being furnished with this office action.
(See Manual of Patent Examining Procedure, section 707.05 (a).)

DLEV011900

US005362755A

United States Patent [19]

Barberich et al.

[11] Patent Number: 5,362,755

[45] Date of Patent: Nov. 8, 1994

[54] METHOD FOR TREATING ASTHMA USING OPTICALLY PURE (R)-ALBUTEROL

[75] Inventors: Timothy J. Barberich, Concord; James W. Young, Still River, both of Mass.

[73] Assignee: Sepracor, Inc., Marlborough, Mass.

[21] Appl. No.: 169,581

[22] Filed: Dec. 7, 1993

Related U.S. Application Data

[63] Continuation of Ser. No. 896,725, Jun. 9, 1992, abandoned, which is a continuation of Ser. No. 461,262, Jan. 5, 1990, abandoned.

[51] Int. Cl.[5] A61K 31/135

[52] U.S. Cl. 514/649; 514/826

[58] Field of Search 514/649, 826

[56] References Cited

FOREIGN PATENT DOCUMENTS

2255503 7/1992 United Kingdom .

OTHER PUBLICATIONS

R. T. Brittain et al., *Br. J. Pharmacol.*, 48:144-147 (1973).

C. J. Hawkins and G. T. Klease, *J. Med. Chemistry*, 16(7):856-857 (1973).

D. Hartley and D. Middlemiss, *J. Med. Chemistry*, 14(9):895 (1971).

C. K. Buckner and P. Abel, *J. Pharmacol. Exp. Ther.*, 189(3):615-625 (1974).

Tan et al., "Analysis of Salbutomol Enantiomers in Human Urine by Chiral High Performance Liquid Chromatography and Preliminaty Studies Related to the Stereoselective Disposition Kinetics in Man", *J. Chromatogr.*, 422, 187-95 (1987).

Chemical Abstracts 89:123259m (1978).

Primary Examiner—Raymond J. Henley, III

Attorney, Agent, or Firm—Heslin & Rothenberg

[57] ABSTRACT

The optically pure R(−) isomer of albuterol, which is substantially free of the S(+) isomer, is a potent bronchodilator for relieving the symptoms associated with asthma in individuals. A method is disclosed utilizing the optically pure R(−) isomer of albuterol for treating asthma while minimizing the side effects associated with chronic administration of racemic albuterol.

7 Claims, No Drawings

Exhibit B

optically pure active isomer of albuterol and another drug) can be administered in one composition or as two separate entities. For example, they can be administered in a single capsule, tablet, powder, or liquid, etc. or as individual compounds. The components included in a particular composition, in addition to optically pure albuterol and another drug or drugs, are determined primarily by the manner in which the composition is to be administered. For example, a composition to be administered in inhalent form can include, in addition to the drug(s), a liquid carrier and/or propellent. A composition to be administered in tablet form can include a filler (e.g., lactose), a binder (e.g., carboxymethyl cellulose, gum arabic, gelatin), an adjuvant, a flavoring agent, a coloring agent and a coating material (e.g., wax or a plasticizer). A composition to be administered in liquid form can include the combination of drugs and, optionally, an emulsifying agent, a flavoring agent and/or a coloring agent.

In general, according to the method of the present invention, the optically pure R(−) isomer of albuterol, alone or in combination with another drug(s), is administered to an individual periodically as necessary to reduce symptoms of asthma.

The present composition and method provide an effective treatment for asthma while minimizing the undesirable side effects associated with albuterol use. These side effects include central nervous system effects, such as tremor, nervousness, shakiness, dizziness and increased appetite, and cardiac effects, such as cardiac arrythmia. In children, side effects, such as excitement, nervousness and hyperkinesia, are reduced when the pure isomer is administered. In addition, teratogenic effects associated with albuterol are believed to reside in the S(+) enantiomer. Thus, administering the pure R(−) isomer may reduce the teratogenic potential associated with albuterol.

Equivalents

Those skilled in the art will recognize, or be able to ascertain, using no more than routine experimentation, many equivalents to the specific embodiments of the invention described herein. Such equivalents are intended to be encompassed in the scope of the following claims.

We claim:

1. A method of treating asthma in an individual with albuterol, while reducing side effects associated with chronic administration of racemic albuterol, comprising chronically administering to the individual a quantity of an optically pure R(−) isomer of albuterol sufficient to result in bronchodilation while simultaneously reducing undesirable side effects, said R isomer being substantially free of its S(+) isomer.

2. A method of claim 1 wherein the amount of the R(−) isomer of albuterol is greater than approximately 90% by weight of total albuterol.

3. A method of claim 2 wherein the amount of the R(−) isomer of albuterol is greater than 99% by weight of total albuterol.

4. A method of claim 1 comprising administering to the individual by inhalation from approximately 30 mcg to approximately 90 mcg of the R(−) isomer of albuterol per dose.

5. A method of claim 1 comprising orally administering to the individual from approximately 1 mg to approximately 8 mg of the R(−) isomer of albuterol two to four times daily.

6. A method of treating asthma in an individual with albuterol, while reducing side effects associated with chronic administration of racemic albuterol, comprising chronically administering to the individual a quantity of an optically pure R(−) isomer of albuterol sufficient to result in bronchodilation while simultaneously reducing undesirable side effects and at least one additional drug selected from the group consisting of bronchodilators, antihistamines and analgesics.

7. A method of claim 6 wherein the analgesic is selected from the group consisting of: aspirin, acetaminophen and ibuprofen.

* * * * *

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

Philip E. Hansen
Heslin & Rothenberg, P.C.
5 Columbia Circle
Albany, NY 12203-5160

COPY MAILED

MAY 30 1995

SPECIAL PROGRAM
EXAMINATION UNIT

In re Application of :
Barberich et al. :
Application No.: 08/335,480 : DECISION ON PETITION
Filed: November 7, 1994 :
Docket No. 0701.027C :

This is a decision on the petition filed December 27, 1994, requesting that the above-identified application be treated as a continuation application under 37 CFR 1.60 and accorded a filing date of November 7, 1994.

The application, which is a continuation application under 37 CFR 1.60, was deposited on November 7, 1994. Application Division mailed a Notice on December 16, 1994, stating that a copy of the prior application specification was missing, specifically noting pages 2 and 3 as being omitted, requiring a copy of the omitted application specification pages, and stating that the filing date of the application would be the date of receipt of the missing items. However, it is noted that prior application Serial No. 08/163,581 issued as Patent No. 5,362,755 on November 8, 1994. Therefore, a filing date on or before November 8, 1994, is necessary to establish copendency between the prior application and the above-identified application in order for the above-identified application to be considered a proper filing under 37 CFR 1.60.

In response on December 27, 1994, a copy of the missing specification pages were filed. The application was erroneously assigned a filing date of December 27, 1994, and the application was forwarded to Group 1200 for examination.

On March 9, 1995, a nonfinal Office action was mailed setting a three month shortened statutory period for response.

Subsequently, the application was forwarded to this Office for review of the petition filed December 27, 1994. The petition, includes a check for the $130.00 petition fee. Petitioner argues that the failure to file a true copy of the prior application, on filing was inadvertent. Petitioner requests that the earlier filing date be accorded this application.

A review of the application file, reveals that a copy of the prior application specification pages 2 and 3 are not among the application papers filed November 7, 1994. Also, 8 total pages of specification, including the claim pages and abstract are identified on the copy of the postcard receipt accompanying the petition; whereas, 10 total pages of specification, including the claims and abstract were present in the prior application. Thus, it is concluded from the available evidence that a true copy of the prior application specification pages 2 and 3 were not submitted, on filing.

37 CFR 1.60(b) states, in part, that if a true copy of the prior application as filed is not filed with the application or if the statement that the application papers are a true copy is omitted, the application will not be given a filing date earlier than the date upon which the copy and statement are filed, unless a petition with the fee as set forth in 37 CFR 1.17(i)(1) is filed which satisfactorily explains the delay in filing these items.

In this application, the failure to file a true copy of the prior application, on filing, has been deemed to be an inadvertent error.

As construed above, the petition to accord the application a filing date of November 7, 1994, is granted.

The application is being forwarded to Application Division for correction of the records to reflect a November 7, 1994, filing date, and for further processing with the filing date of November 7, 1994, as a continuation application under 37 CFR 1.60 of prior application Serial No. 08/163,581, using the application papers filed November 7, 1994, and the copy of pages 2 and 3 of the prior application specification filed December 27, 1994.

Thereafter, the application will be returned to Examining Group 1200 to await response to the March 9, 1995, office action. The three month shortened statutory period for response continues to run from the March 9, 1995, date of mailing of that office action.

Peter Kratz for

Fred A. Silverberg
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

PK